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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,930	10/03/2001	Thelka Kurz	MERCK 2293	4412

23599 7590 10/29/2002

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 10/29/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,930

Applicant(s)

KURZ ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/22/02&8/15/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-30 is/are pending in the application.
- 4a) Of the above claim(s) 15,17,29 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,14,16,18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 15, 17, 29 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

1. Applicant's election with traverse of species defined in claim 16 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the claims are in proper form of Markush group. This is not found persuasive because species election requirement is proper for Markush claim. Applicants may not confuse restriction and species election. See MPEP 803.02.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objection

2. Claim 13 is objected to because of the following informalities: the word "phrase" in the last line appears to be a typographic error. Appropriate correction is required.

Claim Rejection 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-14, 16, 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. The term "rapidly" in claim 13 is a relative term which renders the claim indefinite. The term "rapidly" is not defined by the claim, the specification does not provide a standard for

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ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The claims are indefinite as to the time period for producing the freeze phase.

3. Claims 18-20 and 23 recite the limitation "lowering the temperature" in line 1 or 2.

There is insufficient antecedent basis for this limitation in the claim.

4. Claims 21-22 recite the limitation "freezing temperature" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 13-14, 16, 18-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gericke (US Patent 5,744,641, of record) in view of Bornstein et al. (US Patent 4,002,748, IDS) or Palepu et al. (U.S. Patent 5,066,647, of record), Franks (IDS).

7. Gericke et al teaches 4-sulfonylbenzoylguanidines, including N-[2-methyl-4,5-bis-(methylsulfonyl)benzoyl]guanidine are known pharmaceutical agents, and may be formulated into pharmaceutical composition in the form of physiological acceptable salts. See, particularly, the abstract, claim 2 and claim 4. A lyophilisate of sulfonylbenzoylguanidine derivative suitable for reconstitution and injection, and the process of making the same. See, particularly, column 25, lines 49-55. The process comprising dissolving the active compound, sterile filtration, transferring the filtered solution to a vial and lyophilization.

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8. Gericke et al. does not teaches expressly the claimed process herein which differs from Gericke's by a warming-up step before lyophilization, or the lyophilisates of particular sulfonylbenzoylguanidines herein.

9. However, Franks teaches that the process of lyophilization is now well understood and the process may be optimized by controlling a variety of factors including shelf temperature, time (for cooling, annealing) etc. See the entire document, particularly, page 222, section 4. What can be controlled. Both Bornstein et al. (US Patent 4,002,748, IDS) or Palepu et al. (U.S. Patent 5,066,647) teach it is desirable to make a reconstitutable lyophilisate for therapeutical purpose. See, particularly, the abstracts. Further, one of ordinary skill in the art would recognize the benefit of rapidly dissolving particle free lyophilisate for injection formulation.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to optimize the lyophilization process including the temperature of shelf and the annealing time, e.g. keeping the solution in the vial at about room temperature (30 °C) for a while before lyophilization.

A person of ordinary skill in the art would have been motivated to optimize the lyophilization process including the temperature of shelf and the annealing time, e.g. keeping the solution in the vial at about room temperature (30 °C) for a while before lyophilization because such optimization is considered a optimization of a result effective parameter, e.g., temperature, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. The composition claims 26-28 are obvious over the cited prior art also because it only differ from the prior art by the process of making. Note a product by process must have elements that are different from the prior art. See, MPEP 2183-2184. No such elements are seen in the claimed

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product. Particularly, since the lyophilisate in Gericke et al. ('680) is suitable for reconstitution and injection, it would have the properties such as reconstitutable and particle free, absent evidence to the contrary.

Response to the Arguments

Applicants' amendments and remarks submitted April 29, 2002 have been fully considered, but are not persuasive for reason discussed below.

Applicants' remarks regarding Frank reference are not persuasive. Particularly, Frank teaches controlling shelf temperature for optimizing the results. The step of warming the solution to certain temperature in the freeze dry is seen to be a matter of optimizing the starting shelf temperature of the drying process.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

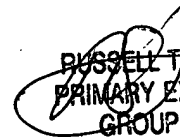
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

October 25, 2002



RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200